DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 16 2007

Re: Namenda
Patent Nos.: 5,061,703
5,614,560
Docket Nos.: 2006E-0332
2006E-0333

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent Nos. 5,061,703 and 5,614,560, filed by Forest Laboratories, Inc., acting as agent for Merz Pharma GmbH & Co. KGaA, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the applications and have determined the regulatory review period for Namenda (memantine hydrochloride), the human drug product claimed by the patent.

The total length of the regulatory review period for Namenda (memantine hydrochloride) is 5,001 days. Of this time, 4,699 days occurred during the testing phase and 302 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: February 7, 1990.

   The applicant claims October 9, 1997, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the original IND effective date was February 7, 1990, which was the date the original IND was removed from clinical hold.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: December 19, 2002.

   FDA has verified the applicant's claim that the new drug application (NDA) for Namenda (memantine hydrochloride) (NDA 21-487) was submitted on December 19, 2002.

3. The date the application was approved: October 16, 2003.

   FDA has verified the applicant's claim that NDA 21-487 was approved on October 16, 2003.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Adda C. Gogoris, Esq.
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